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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,660	07/29/2003	Assaf Govari	BIO-178	6441

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PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
RAMIREZ, JOHN FERNANDO	

ART UNIT	PAPER NUMBER
3737	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/629,660	GOVARI ET AL.	
	Examiner	Art Unit	
	JOHN F. RAMIREZ	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *1-5,11,16,18,20-24 and 33-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-10,12-15,17,19 and 25-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

DETAILED ACTION

Response to Arguments

Applicant's election with traverse in the reply filed on 05/08/08 is acknowledged. This is found persuasive and therefore the requirement is WITHDRAWN. However, upon further consideration, the following office action is provided in response to applicant's arguments filed on 01/09/08.

Applicant's arguments with respect to claims 6, 25, 26 and 29 have been considered but are moot in view of the new ground(s) of rejection.

Applicant alleges that none of the cited prior art references teach or suggest a wireless position sensor that transmits signals for determining six position and orientation coordinates of the wireless position sensor and a signal processing unit for receiving signals from the positions sensor and determining six position and orientation coordinates of the position sensor. However, upon further consideration, a new prior art reference has been found relevant to the new amended independent claims 6, 25, 26 and 29.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6, 13, 15, 16, 19, 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kung (US 6,366,817) in view of Ben-Haim et al. (WO 96/05768).

The Kung patent discloses an apparatus for use in an invasive medical procedure, including: a wireless medical device, which is adapted to be inserted into a body of a subject (see Abstract), the device including a power circuit (see figures 1 and 3, elements 130, 140, 310), which is adapted to be driven inductively by a radio-frequency (RF) electromagnetic field so as to provide operating energy to the device; a power transmitter (column 21, lines 3-17), which is adapted to generate the RF electromagnetic field in a vicinity of the body; and a passive energy transfer amplifier (abstract, figure 2, element 230), which is adapted to be placed in proximity to the medical device so as to enhance inductive driving of the power circuit of the wireless medical device by the RF electromagnetic field (column 21, lines 3-17), wherein the passive energy

transfer amplifier (230) is adapted to be fixed externally to the body in proximity to an area of the body into which the medical device is inserted (column 1, lines 47-65), wherein the sensor comprises a position sensor (column 4, lines 27-40), which is adapted to provide an indication of a location of the probe within the heart, wherein the medical device comprises a sensor (column 4 , lines 27-65), which is adapted to sense a parameter within the body, and a signal transmitter (column 21, lines 3-17), which is coupled to transmit a signal indicative of the parameter to a receiver outside the body, wherein the position sensor comprises a sensor coil (see figures 1 and 3) , and wherein the apparatus further comprises one or more field generators (column 5, lines 1-35), which are adapted to generate energy fields in a vicinity of the medical device, which cause currents to flow in the sensor coil responsively to the position coordinates of the medical device (column 7, lines 22-67, and column 8, lines 1-54), wherein the medical device is adapted to apply at least a portion of the operating energy to tissue in the body (column 1, lines 20-35), wherein the medical device comprises an electrode (inherent by disclosure), which is adapted to apply electrical energy to the tissue (column 1, lines 20-35), and a wireless medical device including a power circuit (see figures 1 and 3, elements 130, 140, 310), which is adapted to be driven inductively by a radio-frequency (RF) electromagnetic field generated by a power transmitter outside the body (column 1, lines 47-65; see figure 1), so as to provide operating energy to the device (see abstract); and a passive energy transfer amplifier (230), which is adapted to be placed in proximity to the medical

device so as to enhance inductive driving of the power circuit of the wireless medical device by the RF electromagnetic field (see abstract).

However, Kung does not teach or suggest a wireless position sensor that transmits signals for determining six position and orientation coordinates of the wireless position sensor and a signal processing unit for receiving signals from the positions sensor and determining six position and orientation coordinates of the position sensor. In the same field of endeavor, Ben-Haim et al. disclose and shows in figures 1, 2 and 4 a locating system having a catheter (10) is inserted into an artery (11) of a patient using standard techniques. Catheter (10) comprises a body (12), a locating sensor (14) and an active portion (16) at the distal end (15) of the catheter. The active portion (16), may include an electrical sensor, an ultrasound head, a fiber optic viewing head, an electrical stimulator, an electrical or laser ablator, a blood pressure or temperature sensor or a cryogenic probe. In general the catheter will include leads, light guides, wave guides, etc. for energizing the active portion in response to commands of an operator. The position and orientation of the distal end of the catheter is ascertained by determining the position of the locating sensor. In a preferred embodiment of the invention, the locating sensor comprises two or three antennas, for example coils which are irradiated by two or three radiators (18, 20 and 22), which are outside the body surface of the patient. These coils generate signals in response to externally applied magnetic fields which allows for the computation of six position and orientation dimensions by a processor unit (26).

Claims 7-12, 14, 17-18, 20-22, and 26-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kung in view of Ben-Haim et al. (WO 96/05768) as applied above, in view of Spillman, Jr. et al.(US 6,206,835), Kuhn et al. (US 6,206,835) and in view of White (US 7,001,346) and Borza (US 5,755,748).`

In reference to **claims 7-11, 14, 17-18 and 20-22**, Kung in view of Ben-Haim et al. teach all the limitations of the claimed subject matter as discussed above, Kung does not disclose a medical implant device including a power transmitter that is adapted to generate the RF electromagnetic field at a predetermined frequency, and wherein the passive energy transfer amplifier has a resonant response at the predetermined frequency, wherein the passive energy transfer amplifier comprises a coil and a capacitance, which are coupled so as to define a resonant circuit having the resonant response at the predetermined frequency, wherein the passive energy transfer amplifier is adapted to be implanted in the body in proximity to the medical device, wherein the medical device comprises a sensor for use in association with an orthopedic implant, and wherein the passive energy transfer amplifier is incorporated in the orthopedic implant, wherein the sensor comprises a position sensor, which is fixed to the implant for use in assessing an alignment of the implant, wherein the medical device comprises a sensor, which is fixed to an invasive probe for insertion into a heart of the subject, and wherein the passive energy transfer amplifier is adapted to be fixed to a chest of the subject, wherein the power circuit of the wireless medical device comprises a coil antenna for receiving the

electromagnetic field, and wherein the signal transmitter is coupled to transmit the signal via the coil antenna, wherein the sensor comprises a position sensor, and wherein the transmitted signal is indicative of position coordinates of the medical device within the body, wherein the parameter that is sensed by the sensor comprises a physiological parameter, wherein the physiological parameter comprises an electrical parameter, wherein the physiological parameter comprises at least one of a temperature, a pressure, a chemical parameter and a flow parameter.

Concerning **claims 12, and 26-28,** Kung in view of Ben-Haim et al. teach all the limitations of the claimed subject matter as discussed above, Kung does not disclose wherein the implant is a hip joint implant, including a femur head element and an acetabulum element, and wherein the passive energy transfer amplifier comprises a coil, which is integrated in the acetabulum element, a prosthetic joint including first and second joint elements, which are adapted to be implanted in a body of a subject; first and second wireless position sensors, which are respectively fixed to the first and second joint elements so as to transmit position signals indicative of an alignment of the first and second joint elements, each of the position sensors including a power circuit, which is adapted to be driven inductively by a radio-frequency (RF) electromagnetic field so as to provide operating energy to the sensors; and a passive energy transfer amplifier, which is fixed to at least one of the first and second joint elements so as to enhance inductive driving of the power circuit of the wireless position sensors by the RF electromagnetic field, wherein the prosthetic joint comprises a

hip joint, and wherein the first and second joint elements comprise a femur head element and an acetabulum element, and wherein the passive energy transfer amplifier is fixed to the acetabulum element, wherein the prosthetic joint comprises a knee joint.

In reference to **claims 29-32**, Kung in view of Ben-Haim et al. teach all the limitations of the claimed subject matter as discussed above, Kung does not disclose an implantable medical device, including a catheter, having a distal end, which is adapted to be inserted into a heart of a subject, the catheter including a wireless position sensor, fixed adjacent to the distal end of the catheter so as to transmit position signals indicative of a position of the catheter within the heart, the position sensor including a power circuit, which is adapted to be driven inductively by a radio-frequency (RF) electromagnetic field so as to provide operating energy to the position sensor, wherein the passive energy transfer amplifier is adapted to be placed on a chest of the subject adjacent to the heart, wherein the wireless position sensor comprises a sensor coil, and wherein the apparatus further comprises one or more field generators, which are adapted to generate energy fields in a vicinity of the heart, wherein the energy fields cause currents to flow in the sensor coil responsively to the position coordinates of the medical device, wherein the catheter further comprises one or more electrodes for sensing electrical activity within the heart.

However, the steps of including a power transmitter that is adapted to generate the RF electromagnetic field at a predetermined frequency, and wherein the passive energy transfer amplifier has a resonant response at the

predetermined frequency, wherein the passive energy transfer amplifier comprises a coil and a capacitance, which are coupled so as to define a resonant circuit having the resonant response at the predetermined frequency, wherein the passive energy transfer amplifier is adapted to be implanted in the body in proximity to the medical device, wherein the medical device comprises a sensor for use in association with an orthopedic implant, and wherein the passive energy transfer amplifier is incorporated in the orthopedic implant, wherein the sensor comprises a position sensor, which is fixed to the implant for use in assessing an alignment of the implant, wherein the medical device comprises a sensor, which is fixed to an invasive probe for insertion into a heart of the subject, and wherein the passive energy transfer amplifier is adapted to be fixed to a chest of the subject, wherein the power circuit of the wireless medical device comprises a coil antenna for receiving the electromagnetic field, and wherein the signal transmitter is coupled to transmit the signal via the coil antenna, wherein the sensor comprises a position sensor, and wherein the transmitted signal is indicative of position coordinates of the medical device within the body, wherein the parameter that is sensed by the sensor comprises a physiological parameter, wherein the physiological parameter comprises an electrical parameter, wherein the physiological parameter comprises at least one of a temperature, a pressure, a chemical parameter and a flow parameter, wherein the implant is a hip joint implant, including a femur head element and an acetabulum element, and wherein the passive energy transfer amplifier comprises a coil, which is integrated in the acetabulum element, a prosthetic joint including first and second

joint elements, which are adapted to be implanted in a body of a subject; first and second wireless position sensors, which are respectively fixed to the first and second joint elements so as to transmit position signals indicative of an alignment of the first and second joint elements, each of the position sensors including a power circuit, which is adapted to be driven inductively by a radio-frequency (RF) electromagnetic field so as to provide operating energy to the sensors; and a passive energy transfer amplifier, which is fixed to at least one of the first and second joint elements so as to enhance inductive driving of the power circuit of the wireless position sensors by the RF electromagnetic field, wherein the prosthetic joint comprises a hip joint, and wherein the first and second joint elements comprise a femur head element and an acetabulum element, and wherein the passive energy transfer amplifier is fixed to the acetabulum element, wherein the prosthetic joint comprises a knee joint, an implantable medical device, including a catheter, having a distal end, which is adapted to be inserted into a heart of a subject, the catheter including a wireless position sensor, fixed adjacent to the distal end of the catheter so as to transmit position signals indicative of a position of the catheter within the heart, the position sensor including a power circuit, which is adapted to be driven inductively by a radio-frequency (RF) electromagnetic field so as to provide operating energy to the position sensor, wherein the passive energy transfer amplifier is adapted to be placed on a chest of the subject adjacent to the heart, wherein the wireless position sensor comprises a sensor coil, and wherein the apparatus further comprises one or more field generators, which are adapted to generate energy

fields in a vicinity of the heart, wherein the energy fields cause currents to flow in the sensor coil responsively to the position coordinates of the medical device, and wherein the catheter further comprises one or more electrodes for sensing electrical activity within the heart are considered conventional in the art as evidenced by the teachings of Spillman, Jr. et al. (US 6,206,835), White (US 7,001,346), Borza (US 5,755,748) and Kuhn et al. (US 6,216,026).

The Spillman, Jr. et al. and the Borza patents teaches a medical implant device including a power transmitter that is adapted to generate the RF electromagnetic field at a predetermined frequency, and wherein the passive energy transfer amplifier has a resonant response at the predetermined frequency, wherein the passive energy transfer amplifier comprises a coil and a capacitance, which are coupled so as to define a resonant circuit having the resonant response at the predetermined frequency, wherein the passive energy transfer amplifier is adapted to be implanted in the body in proximity to the medical device, wherein the medical device comprises a sensor for use in association with an orthopedic implant, and wherein the passive energy transfer amplifier is incorporated in the orthopedic implant, wherein the sensor comprises a position sensor, which is fixed to the implant for use in assessing an alignment of the implant, wherein the medical device comprises a sensor, which is fixed to an invasive probe for insertion into a heart of the subject, and wherein the passive energy transfer amplifier is adapted to be fixed to a chest of the subject, wherein the power circuit of the wireless medical device comprises a coil antenna for receiving the electromagnetic field, and wherein the signal transmitter is

coupled to transmit the signal via the coil antenna, wherein the sensor comprises a position sensor, and wherein the transmitted signal is indicative of position coordinates of the medical device within the body, wherein the parameter that is sensed by the sensor comprises a physiological parameter, wherein the physiological parameter comprises an electrical parameter, wherein the physiological parameter comprises at least one of a temperature, a pressure, a chemical parameter and a flow parameter (from Spillman, Jr. et al., see Abstract, column 1, lines 10-26, and lines 57-65, column 3, lines 35-67, see figures 1-4 and related description) (from Borza, see column 3, lines 24-42; column 6, lines 16-25 and lines 55-67).

Moreover, the White patent teaches wherein the implant is a hip joint implant, including a femur head element and an acetabulum element, and wherein the passive energy transfer amplifier comprises a coil, which is integrated in the acetabulum element, a prosthetic joint including first and second joint elements, which are adapted to be implanted in a body of a subject; first and second wireless position sensors, which are respectively fixed to the first and second joint elements so as to transmit position signals indicative of an alignment of the first and second joint elements, each of the position sensors including a power circuit, which is adapted to be driven inductively by a radio-frequency (RF) electromagnetic field so as to provide operating energy to the sensors; and a passive energy transfer amplifier, which is fixed to at least one of the first and second joint elements so as to enhance inductive driving of the power circuit of the wireless position sensors by the RF electromagnetic field, wherein the

prosthetic joint comprises a hip joint, and wherein the first and second joint elements comprise a femur head element and an acetabulum element, and wherein the passive energy transfer amplifier is fixed to the acetabulum element, wherein the prosthetic joint comprises a knee joint (see abstract and figures 2 and 14).

And furthermore, the Kuhn et al. patent teaches an implantable medical device, including a catheter, having a distal end, which is adapted to be inserted into a heart of a subject, the catheter including a wireless position sensor, fixed adjacent to the distal end of the catheter so as to transmit position signals indicative of a position of the catheter within the heart, the position sensor including a power circuit, which is adapted to be driven inductively by a radio-frequency (RF) electromagnetic field so as to provide operating energy to the position sensor, wherein the passive energy transfer amplifier is adapted to be placed on a chest of the subject adjacent to the heart, wherein the wireless position sensor comprises a sensor coil, and wherein the apparatus further comprises one or more field generators, which are adapted to generate energy fields in a vicinity of the heart, wherein the energy fields cause currents to flow in the sensor coil responsively to the position coordinates of the medical device, wherein the catheter further comprises one or more electrodes for sensing electrical activity within the heart (see abstract and figures 2 and 4).

Based on the above observations, for a person of ordinary skill in the art, modifying the method disclosed by Kung with the above discussed enhancements would have been considered obvious because such modifications

would have improved the performance and to help monitor and evaluate the condition of the implant device.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN F. RAMIREZ whose telephone number is (571)272-8685. The examiner can normally be reached on (Mon-Fri) 7:00 - 3:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian L Casler/
Supervisory Patent Examiner, Art Unit 3737

/J. F. R./
Examiner, Art Unit 3737